

91

Claims

1. A device for administering an active agent
5 to the skin or mucosa of an individual comprising a
laminated composite of:
- (a) a backing layer;
- (b) an active agent-permeable membrane, the
backing layer and membrane defining
- 10 (c) a reservoir therebetween that contains a
formulation of the active agent, said reservoir having a
smaller periphery than the backing layer and membrane such
that a portion of the backing layer and membrane extends
outwardly of the periphery of the reservoir;
- 15 (d) a first peelable active agent formulation-
impermeable layer that underlies the reservoir and a por-
tion of said outwardly extending portion of the backing
layer and membrane;
- (e) an adhesive layer that underlies and covers
- 20 the first peelable active agent formulation-impermeable
layer and said outwardly extending portion of the backing
layer and membrane;
- (f) a second peelable active agent formulation-
impermeable layer that underlies and covers the adhesive
- 25 layer;
- (g) a permanent heat seal about the periphery of
the reservoir between the backing layer and the membrane;
and
- (h) a peelable heat seal between the membrane
- 30 and the first peelable active agent formulation-
impermeable layer located underneath and at a radius not
less than that of the permanent heat seal, said permanent
and peelable heat seals providing barriers to migration of
components of the active agent formulation from the
- 35 reservoir into the adhesive layer and said first and
second peelable active agent impermeable layers being

bonded together such that when the second peelable layer is removed from the device the peelable heat seal is broken and the first peelable layer and underlying portion of the adhesive layer is removed therewith.

5

2. The device of claim 1 wherein the adhesive is incompatible with one or more of the components of the formulation that permeate through the membrane to the skin or mucosa.

10

3. The device of claim 1 wherein the backing layer is a laminated composite of at least one layer that is impermeable to the formulation and an inner heat-sealable layer. 0

15

4. The device of claim 1 wherein the adhesive is an acrylic adhesive, the active agent is pindolol hydrochloride, and the formulation includes ethyl alcohol and glycerol monooleate.

20

5. The device of claim 1 wherein the adhesive is an acrylic adhesive, the active agent is nicardipine hydrochloride, and the formulation includes ethyl alcohol and glycerol monooleate.

25

6. The device of claim 1 wherein the adhesive is a silicone adhesive, the active agent is calcitriol and the formulation includes ethanol, methyl laurate, and water.

30

35